

Remarks

Claims 1 and 3- 28 were pending in the subject application. By this Amendment, claim 1 has been amended, and claims 3, 7, 13, and 17-28 have been cancelled. The undersigned avers that no new matter is introduced by this amendment. Support for the amendments can be found throughout the subject specification and in the claims as originally filed. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 1, 4-6, 8-12, and 14-16 are currently before the Examiner for consideration. Favorable consideration of the pending claims is respectfully requested.

Submitted herewith is a Request for Continued Examination (RCE) under 37 CFR §1.114 for the subject application.

Claims 1, 7 and 13-15 have been rejected under 35 U.S.C. §102(b) as being anticipated by Bot *et al.* (WO 00/00215). Applicant respectfully traverses this ground for rejection because the cited reference does not disclose each and every element of the claimed invention.

By this Amendment, Applicant has amended claim 1 to incorporate the subject matter of claim 3, which recites that the concentration of the carbohydrate is from 2% w/v to 70% w/v, and claim 7, which recites an outlet temperature of 20°C to 40°C. Please note that claim 3 was not included in the rejection under §102(b). The cited reference does not disclose the use of trehalose at a concentration from 2% w/v to 70% w/v nor an outlet temperature of 20°C to 40°C, as recited in claim 1 as currently amended. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631; 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131. As the Bot *et al.* publication does not teach each element of the claimed method, the Bot *et al.* publication does not anticipate the claimed method. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §102 based on Bot *et al.*

Claims 3-6 and 8-11 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Bot *et al.* (WO 00/00215) as applied to claim 1. Furthermore, claim 16 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Bot *et al.* (WO 00/00215) as applied to claim 1 and

further in view of LiCalsi *et al.* (*Vaccine*, 1999, 17:1796-1803). Applicant respectfully traverses this ground of rejection.

Please note that claim 3 has been cancelled herein; however, to the extent that this rejection might be applied to the claims now presented for examination, Applicant respectfully traverses because the cited reference does not disclose or suggest Applicant's unique and advantageous method for producing a micro-particle dry powder.

The method of the invention as presently claimed is carried out by spray drying a virus and 2% – 70% w/v trehalose using an outlet temperature of 20°C to 40°C. The Bot *et al.* reference describes a process utilizing different conditions. There is no motivation to modify the Bot *et al.* process to successfully arrive at the invention as now claimed.

The Bot *et al.* publication does not teach the method of claim 1 (from which all the rejected claims depend), whereby a mixture of viral particle and 2% w/v to 70% w/v trehalose are spray dried using an outlet temperature of 20°C to 40°C. Furthermore, although Bot *et al.* disclose that trehalose can be used as an excipient to provide structure, *i.e.*, to confer rigidity (see page 24, lines 13-20), no specific amount of trehalose is mentioned at page 24. The Office Action cites Example XIV of the Bot *et al.* publication as being relevant for the non-obviousness of the claims. However, this example relates to the preparation of microparticles by spray drying a virus with hydroxyethyl starch using an outlet temperature of 61° C. The hydroxyethyl starch in the feedstock of Example XIV is low (1 mg), approximately 0.5% in the feedstock, which is less than the concentration of trehalose recited in claim 1. Examples XV and XVI (pages 62-63) also indicate that viability was only approximately 1%. This is in contrast to the method of the present invention, in which 60% - 70% recovery was achieved (see page 12, line 21, and Figure 1 of the subject specification). Thus, the claimed method requires parameters not taught in the cited reference and which result in improved viability.

The mere fact that the purported prior art could have been modified or applied in some manner to yield an applicant's invention does not make the modification or application obvious unless "the results would have been predictable to one of ordinary skill in the art." *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007); MPEP §2143.01. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a) is respectfully requested.

Claims 1 and 3-16 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Sutton *et al.* (WO 97/36578) and further in view of Roser *et al.* (U.S. Patent No. 6,190,701) and LiCalsi *et al.* (*Vaccine*, 1999, 17:1796-1803). Applicant respectfully traverses this ground of rejection.

By this Amendment, Applicant has amended claim 1 to incorporate the subject matter of claim 13. The method of the invention as presently claimed is carried out by spray drying a virus and 2%-70% w/v trehalose using an outlet temperature of 20°C to 40°C, and a drying airflow rate of 4.8L/sec to 8L/sec. Sutton *et al.* uses sucrose, and does not disclose the use of trehalose as a stabilizing carbohydrate. Sutton *et al.* also does not disclose a drying airflow rate of from 4.8L/sec to 8L/sec. Page 9, line 25 of Sutton *et al.* discloses that a low outlet temperature is desirable due to the heat-sensitive nature of DNA, but that reducing the temperature increases particle size due to agglomeration. The agglomeration is caused by high moisture content. To avoid this, Sutton *et al.* teach that an outlet temperature of 70°C is favored (page 9, lines 30-31 of Sutton *et al.*).

Therefore, although Example 3 has an outlet temperature of 39.9°C, the Sutton *et al.* publication makes it clear that higher outlet temperatures are preferred (this is contrary to the present invention). Also, it is to be assumed, based on the above, that the particles of Example 3 would have high moisture content and would agglomerate. This is in contrast to the present invention, in which the process, with high drying air flow rate, results in a dry product (see page 11, line 16, of the subject specification, which states that increasing air flow rate improves drying). Therefore, even if one of ordinary skill in the art substituted sucrose for trehalose, they would still want to use a higher outlet temperature than that specified in claim 1 as amended and would not achieve the same viability levels. The other references, Roser *et al.* and LiCalsi *et al.*, do not cure the deficiencies of the Sutton *et al.* publication. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicant's agreement with or acquiescence in the Examiner's position.

In view of the foregoing remarks and amendments to the claims, Applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

Applicant invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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